

### REMARKS

The Office action of June 11, 2002, has been carefully considered.

The specification has been amended to add proper subject matter headings.

Claims 11 through 22 have been rejected under 35 USC 102(b) or under 35 USC 103 over PCT Publication WO 96/25954, having a publication date of August 29, 1996. In discussing this rejection, reference will be made to the corresponding U.S. Patent No. 6,106,807.

The claimed invention is directed to novel copolymers comprising at least one sequence having a hydrophilic character and at least one sequence having a hydrophobic character. The sequence having a hydrophobic character include a homopolymer having recurring units of methylenemalonate. Typical hydrophilic units are recited in Claim 14.

The Albayrak et al reference is directed to polymerization of 1-ethoxycarbonyl-1-ethoxycarbonylmethylene oxycarbonyl-ethene, which is referred to in the present application as MM 2.1.2 at page 9, line 25 through page 10, line 4. The Albayrak et al reference is directed to microparticles having a wall material of polymerized methylenemalonate diesters. The Office action takes the position

that because such materials are polymerized in the presence of either polyvinylpyrrolidone (Example 12) or Pluronic® F 68 (Example 15), the resulting polymer is therefore a copolymer having hydrophilic units and hydrophobic units, where the hydrophobic units are based on methylenedimaleonate.

Applicants believe that the position taken in the Office action is incorrect. While Applicants do not wish to claim herein the process for forming the polymers of the invention, it is noted from consideration of the specification at page 5, lines 7 through 10, that the polymers of the invention can be prepared by anionic polymerization, radical polymerization or the technique of coupling precursor sequences of the copolymer, these sequences having been adequately functionalized beforehand on the chain end. A detailed discussion of these processes is found in the specification on page 5, line 4 through page 8, line 13. Moreover, from review of the examples of the present application, it can be seen that the polymerization is commonly carried out in an organic medium in the presence of an initiator.

The above discussion is set forth not to limit the scope of the invention, but to demonstrate that specific processes and techniques are necessary in order to obtain the desired block copolymer from the starting materials. Such

necessary processes are not carried out in the Albayrak et al patent.

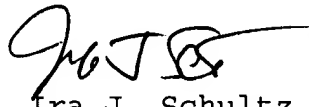
Thus, according to the examples of Albayrak et al the monomer is dispersed in an aqueous phosphate buffer in the presence of material such as dextran-8, polyvinylpyrrolidone or Pluronic® F 68. Albayrak et al discloses at column 3, lines 16 through 20, that various materials may be added to the polymerization mixture as surface active substances, and it is assumed that this is the purpose of the specific materials added. These materials serve as surface active agents to facilitate the preparation of microparticles, and they will not enter into the polymerization reaction in the absence of special provisions being taken to cause them to enter into the polymerization reaction. For example, an initiator may cause copolymerization to take place with these materials, but Albayrak et al does not disclose or suggest the use of an initiator.

Thus, Albayrak et al obtains microparticles formed from a homopolymer of methyldene malonate, and does not obtain particles containing a copolymer of methyldene malonate units and hydrophilic units.

Withdrawal of this rejection is accordingly requested.

In view of the foregoing amendments and remarks,  
Applicants submit that the present application is now in  
condition for allowance. An early allowance of the  
application is earnestly solicited.

Respectfully submitted,



Ira J. Schultz  
Registration No. 28666

LAW OFFICES  
DENNISON, SCHULTZ & DOUGHERTY  
612 CRYSTAL SQUARE 4  
1745 JEFFERSON DAVIS HIGHWAY  
ARLINGTON, VIRGINIA 22202-3417

703 412-1155